NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE METFORMIN MARKETING AND SALES PRACTICE LITIGATION	**Civil Action No. 20-2324** **OPINION**

ARLEO, UNITED STATES DISTRICT JUDGE

THIS MATTER comes before the Court on Motions to Dismiss the First Amended Complaint ("FAC"), ECF No. 128, brought by: (1) the Manufacturer Defendants,[1] ECF No. 132; and (2) the Pharmacy Defendants[2] and AvKare, ECF No. 133. Plaintiffs[3] oppose both Motions. ECF Nos. 134, 135. For the reasons explained below, each Motion to Dismiss is **GRANTED IN PART** and **DENIED IN PART**.

I. FACTUAL BACKGROUND

[1] The Manufacturer Defendants are Actavis Pharma, Inc., Actavis, LLC, Amneal Pharmaceuticals LLC, Ascend Laboratories, LLC, Aurobindo Pharma USA, Inc., Aurobindo Pharma, Ltd., Aurolife Pharma, LLC, AvKare Inc., Emcure Pharmaceuticals, Granules Pharmaceuticals, Inc., Granules USA, Inc., Heritage Pharmaceuticals, Inc., Teva Pharmaceutical Industries, Inc., Teva Pharmaceutical Industries, Ltd., and Teva Pharmaceuticals USA Inc.

[2] The Pharmacy Defendants are CVS Health Corporation, Rite-Aid Corporation, Walgreens Boot Alliance, Inc., and Walmart Stores, Inc.

[3] There are eight proposed Class Representative Plaintiffs in the instant action. First, seven Plaintiffs seek to represent the interests of consumers who purchased Defendants' metformin-containing drugs ("MCDs") (the "Consumer Plaintiffs"): Joseph Brzozowski and Jacqueline Harris (citizens and residents of New Jersey), Michael Hann, Mohammad Rahman, and Elaine Wohlmuth (citizens and residents of California), Stelios Mantalis (citizen and resident of New York), and Kristin Wineinger (citizen and resident of Indiana). Second, one Plaintiff, MSP Recover Claims, Series LLC ("MSPRC"), seeks to represent the interests of third-party payors ("TPPs") who made co-payments for Defendants' MCDs.

This putative class action arises out of the allegedly adulterated, misbranded, and/or unapproved manufacturing, sale, and distribution of MCDs. See generally FAC.[4] MCDs are commonly used in the treatment and management of type 2 diabetes. Id. ¶ 2. Defendants allegedly manufactured, distributed, and sold MCDs that were contaminated with a probable human carcinogen known as N-nitrosodimethylamine ("NDMA"), id. ¶¶ 8, 27. Plaintiffs are consumers who purchased MCDs and MSPRC, an LLC that has been assigned the rights and power to sue Defendants on behalf of the TPPs. Id. ¶¶ 12-18, 19-27. The TPPs allege that they have made payments for contaminated MCDs in all fifty states. Id. ¶ 27.

II. PROCEDURAL HISTORY

On March 3, 2020, Plaintiffs filed their initial Complaint, ECF No. 1, which they subsequently amended on July 6, 2020, ECF No. 58. On May 20, 2021, the Court dismissed the Amended Complaint for lack of standing, and Plaintiffs filed the operative FAC on June 21, 2021. The FAC asserts eleven causes of action against Defendants: (1) breach of express warranty (Counts One and Two); (2) breach of implied warranty of merchantability (Counts Three and Four); (3) breach of warranty under the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301, et seq. (the "MMWA") (Counts Five and Six); (4) fraud (Counts Seven and Eight); (5) negligent misrepresentation and omission (Counts Nine and Ten); (6) violation of state consumer protection laws (Counts Eleven and Twelve); (7) unjust enrichment (Counts Thirteen and Fourteen); (8) negligence (Counts Fifteen and Sixteen); (9) negligence per se (Counts Seventeen and Eighteen); (10) violation of California's Consumer Legal Remedies Act, Cal. Civ. Code §§ 1750, et seq. (Counts Nineteen and Twenty); and (11) violation of New York General Business Law

[4] The Court discussed the background in its Order dated May 20, 2021 (the "May 2021 Order"), ECF No. 124, and thus this Opinion discusses the relevant facts only to the extent necessary to resolve the instant Motions.

§ 349.[5] FAC ¶¶ 342-570 (Counts Twenty One and Twenty Two). The instant Motions to dismiss the FAC pursuant to Federal Rules of Civil Procedure 12(b)(1), 12(b)(2), and 12(b)(6) followed.

III. LEGAL STANDARD

A motion to dismiss for lack of standing is properly brought pursuant to Rule 12(b)(1). See Bellentine v. United States, 486 F.3d 806, 810 (3d Cir. 2007). Under Rule 12(b)(1), a plaintiff bears the burden of persuading the Court that subject matter jurisdiction exists. See Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d 1406, 1409 (3d Cir. 1991). In resolving a Rule 12(b)(1) motion, a court first determines whether the motion presents a "facial" or "factual" attack. See Constitution Party of Pa. v. Aichele, 757 F.3d 347, 357 (3d Cir. 2014). A facial attack argues that a claim on its face "is insufficient to invoke the subject matter jurisdiction of the court," id. at 358, and "does not dispute the facts alleged in the complaint," Davis v. Wells Fargo, 824 F.3d 333, 346 (3d Cir. 2016). A court reviewing a facial attack must "consider the allegations of the complaint and documents referenced therein and attached thereto, in the light most favorable to the plaintiff." Constitution Party of Pa., 757 F.3d at 358. Here, Defendants' motions to dismiss for lack of standing present facial attacks because they challenge Plaintiffs' standing to bring this lawsuit according to the pleaded facts. See Mfr. Def. Mem. at 13-22, ECF No. 132.1; Pharmacy Def. Mem. at 4-9, ECF No. 133.1. The Court thus accepts the pleaded facts as they relate to Plaintiffs' standing as true and draws all reasonable inferences in Plaintiffs' favor. See Constitution Party of Pa., 757 F.3d at 358.

In considering a Rule 12(b)(6) motion to dismiss, the Court accepts all pleaded facts as true, construes the complaint in the plaintiff's favor, and determines "whether, under any

[5] The FAC asserts eleven counts on behalf of the Consumer Plaintiffs against all Defendants, and eleven counts on behalf of MSPRC against only the Manufacturer Defendants. FAC ¶¶ 342-570.

reasonable reading of the complaint, the plaintiff may be entitled to relief." Phillips v. County of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008) (internal quotation marks and citation omitted). To survive a motion to dismiss, the claims must be facially plausible, meaning that the pleaded facts "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). The allegations must be "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007).

To survive a Rule 12(b)(2) motion to dismiss for lack of personal jurisdiction, Plaintiffs bear the burden of proving that personal jurisdiction is proper. IMO Indus., Inc. v. Kiekert AG, 155 F.3d 254, 257 (3d Cir. 1998). In establishing a prima facie case of personal jurisdiction, a plaintiff is "entitled to have [his] allegations taken as true and all factual disputes drawn in [his] favor." O'Connor v. Sandy Lane Hotel Co., 496 F.3d 312, 316 (3d Cir. 2007) (citation and quotations omitted). However, where a Rule 12(b)(2) motion challenges a plaintiff's allegations with "affidavits or other evidence," the "plaintiff must respond with actual proofs, not mere allegations." UniMaven, Inc. v. Texas TR, LLC, No. 17-12008, 2018 WL 2244695, at *2 (D.N.J. Apr. 25, 2018) (quoting Patterson v. FBI, 893 F.2d 595, 604 (3d Cir. 1990)).

IV. ANALYSIS

A. Standing

Defendants argue that the Court should dismiss the FAC because Plaintiffs failed to correct the deficiencies the Court identified in its May 2021 Order with respect to their lack of Article III standing to bring this action. See Mfr. Def. Mem. at 13-22, Pharmacy Def. Mem. at 4-9. The Court agrees as to the Consumer Plaintiffs but finds that MSPRC has sufficiently alleged its standing to bring claims against the Manufacturer Defendants.

Litigants seeking to invoke federal jurisdiction must establish that they have standing to sue. Lujan v. Defs. of Wildlife, 504 U.S. 555, 561 (1992). To do so, a plaintiff must allege three essential elements: (1) a "concrete and particularized" injury-in-fact; (2) a "causal connection between the injury and the conduct complained of"; and (3) "a likelihood that the injury will be redressed by a favorable decision." In re Horizon Healthcare Servs. Inc. Data Breach Litig., 846 F.3d 625, 633 (3d Cir. 2017) (citing Lujan, 504 U.S. at 560-61). To establish an injury in fact, a plaintiff "must show that he or she suffered 'an invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or imminent,' not conjectural or hypothetical." Ellison v. Am. Bd. of Orthopaedic Surgery, 11 F.4th 200, 205 (3d Cir. 2021) (quoting Spokeo, Inc. v. Robins, 578 U.S. 330, 339 (2016)). The causation element requires a plaintiff to establish that the alleged injury "is fairly traceable to the challenged conduct of the defendant." Mielo v. Steak 'N Shake Operations, Inc., 897 F.3d 467, 480-81 (3d Cir. 2018) (quoting Spokeo, 578 U.S. at 338).

The Court previously found that Plaintiffs lacked standing because (1) the Consumer Plaintiffs failed to demonstrate that they suffered an injury, as they did not allege that they purchased or ingested any MCDs containing NDMA[6] and (2) both the Consumer Plaintiffs and MSPRC did not show causation because they failed to connect each Defendants' actions to at least one injured Plaintiff. May 2021 Order at 3-4. While the FAC contains new allegations specifying which Defendants manufactured and sold MCDs to each Consumer Plaintiff, see FAC ¶¶ 12-18, the FAC still lacks any allegations that the MCDs the Consumer Plaintiffs purchased were contaminated by NDMA.

[6] By contrast, the Court previously found that MSPRC adequately alleged that it suffered an injury. May 2021 Order at 3.

Specifically, the Consumer Plaintiffs allege only that they purchased "a product that was not the same as the RLD [(reference listed drug)]," which is the same language the Court previously rejected as insufficient. May 2021 Order at 3. The Consumer Plaintiffs are seeking to represent a class of consumers who paid for "Defendants' MCDs [that] were adulterated and/or misbranded . . . through contamination with [NDMA]." FAC ¶ 8. However, without any allegations that the Consumer Plaintiffs actually purchased MCDs that were contaminated with NDMA, they lack standing to bring such a class action. See Lujan, 504 U.S. at 563 (quoting Sierra Club v. Morton, 405 U.S. 727, 734-35 (1972)) ("[T]he 'injury in fact' test requires more than an injury to a cognizable interest. It requires that the party seeking review be himself among the injured."). The Court therefore dismisses the FAC as to the Consumer Plaintiffs and grants Defendant's motions as to Counts One, Three, Five, Seven, Nine, Eleven, Thirteen, Fifteen, Seventeen, Nineteen, and Twenty-One.

As for MSPRC, the Court is satisfied that MSPRC has now sufficiently alleged which Manufacturer Defendant caused each of its injuries. The FAC contains a chart of sample payments that MSPRC's assignors made for Defendants' MCDs, including the name of each assignor, the unique National Drug Code (NDC) associated with the purchase, and the Defendant who manufactured the MCD. FAC ¶ 27. Bearing in mind the reduced burden of proof required at the pleadings stage, these allegations suffice to trace MSPRC's alleged injuries to specific defendants. Mielo, 897 F.3d at 481 ("While Plaintiffs will face a heavier burden to establish causation should they eventually be put to their proof, their burden of establishing causation at the pleadings stage is less stringent.").[7]

[7] Defendants additionally maintain that MSPRC's allegations of causation are lacking because they allege that groups of two or three related Manufacturer Defendant entities caused each injury, rather than identifying which singular Defendant was responsible for each injury. Mfr. Def. Mem. at 19-20, Pharmacy Def. Mem. at 6-8. The Court finds

The Manufacturer Defendants contend that MSPRC's allegations are insufficient to show a causal connection because MSPRC does not allege that its assignors had to reimburse new or additional purchases or pay more because of alleged impurities, thereby failing to trace the Manufacturer Defendants' conduct to a specific loss by the TPPs. Mfr. Def. Mem. at 20 n.8. This argument is unavailing. MSPRC has alleged that its assignors made payments for contaminated MCDs that were directly traceable to the Manufacturer Defendants and that those MCDs are now worthless, causing economic loss to the TPPs. FAC ¶¶ 27, 277. These allegations are enough to establish that "the defendant's challenged actions, and not the actions of some third party, caused the plaintiff's injury"–the purchase of worthless MCDs. Lujan, 504 U.S. at 560. MSPRC has thereby satisfied the necessary elements of standing.

Lastly, Defendants assert that Plaintiffs lack standing to bring claims across all fifty states, as MSPRC alleges residence in Delaware and Florida and asserts claims for reimbursements made only in six states–Connecticut, Florida, Maryland, New York, and Ohio. Mfr. Def. Mem. at 21-22, Pharmacy Def. Mem. at 8-9. However, this argument "conflates Article III standing with the requirements of Rule 23" class certification. Mielo, 897 F.3d at 480; see also In re Thalomid & Revlimid Antitrust Litig., No. 14-6997, 2015 WL 9589217, at *58 (D.N.J. Oct. 29, 2015) (finding that defendant's "attack on plaintiff's standing to pursue state law claims on behalf of absent class

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this argument unpersuasive. The FAC plausibly alleges that the contaminated MCDs are "fairly traceable" to actions by the Manufacturer Defendants and "the causation element of standing is not an onerous hurdle." Fero v. Excellus Health Plan, Inc., 236 F. Supp. 3d 735, 759 (W.D.N.Y. 2017).

Moreover, this case is distinguishable from In re Valsartan, Losartan & Irbesartan Prods. Liab. Litig., No. 2875, 2021 WL 100204 (D.N.J. Jan. 12, 2021), on which Defendants rely. There, the Court noted that there were a significant number of Defendants in the litigation that were assigned to groups of dozens of defendants and as to whom no class representatives alleged a traceable injury. Id. at 52-53. By contrast, here, MSPRC has traced an injury to each of the Defendants named in the FAC.

members is not an Article III jurisdictional issue"). At this stage of the litigation, MSPRC need only show that it has Article III standing to bring a claim, which it has done successfully.

B. Personal Jurisdiction and Service

Finally, the Manufacturer Defendants argue that this Court lacks personal jurisdiction over the Foreign Defendants[8] because of a lack of minimum contacts and improper service. Mfr. Def. Mem. at 64-69. The Court agrees.

(1) Minimum Contacts

The Due Process Clause permits "two kinds of personal jurisdiction: general (sometimes called all-purpose) jurisdiction and specific (sometimes called case-linked) jurisdiction." Ford Motor Co. v. Montana Eighth Jud. Dist. Ct., 141 S. Ct. 1017, 1024 (2021).[9] MSPRC does not argue that the Foreign Defendants are subject to general jurisdiction, and so the Court addresses only specific jurisdiction.

To establish specific jurisdiction over the Foreign Defendants, MSPRC bears the burden to establish that (1) that the Foreign Defendants "purposefully avail[ed] itself of the privilege of conducting activities within the forum State" through deliberate contacts with New Jersey; and (2) that the plaintiff's claims "arise out of or relate to the defendant's contacts" with the forum. Ford Motor Co., 141 S. Ct. at 1024-25 (citations and quotation marks omitted). The "purposeful availment" requirement assures that the defendant could reasonably anticipate being haled into court in the forum and is not haled into a forum as a result of "random," "fortuitous," or

[8] The "Foreign Defendants" are Teva Pharmaceutical Industries Ltd., Emcure Ltd., Alkem Laboratories, Ltd., and Aurobindo Pharma Ltd.

[9] "A federal court sitting in New Jersey has jurisdiction over parties to the extent provided under New Jersey state law." Miller Yacht Sales, Inc. v. Smith, 384 F.3d 93, 96 (3d Cir. 2004) (citations omitted). The New Jersey long-arm statute "permits the exercise of personal jurisdiction to the fullest limits of due process." IMO Indus., Inc. v. Kiekert AG, 155 F.3d 254, 259 (3d Cir. 1998) (citations omitted).

"attenuated" contacts with the forum state. See World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 297 (1980); see also Burger King Corp., 471 U.S. at 472, 475 (internal citations omitted).

Though a plaintiff generally must demonstrate independent personal jurisdiction over each defendant, Bristol-Myers Squibb Co. v. Superior Ct. of Cal., San Francisco Cnty., 137 S. Ct. 1773, 1783 (2017), the activities of a subsidiary may be imputed to its parent company where the "subsidiary is merely the agent of a parent corporation, or if the parent corporation otherwise 'controls' the subsidiary," Shuker v. Smith & Nephew, PLC, 885 F.3d 760, 781 (3d Cir. 2018) (citations omitted). Here, MSPRC does not argue that the Foreign Defendants have deliberately contacted New Jersey but attempts to establish personal jurisdiction over certain parties under alter ego and agency theories.

Specifically, MSPRC contends that Aurobindo Pharma USA, Inc. and Teva USA Pharmaceuticals, Inc. are the alter egos or agents of Aurobindo Pharma Ltd. and Teva Pharmaceutical Industries Ltd., respectively. Pl. Opp. at 104-05, ECF No. 134.[10] Nonetheless, the FAC is scant with any factual basis to assert personal jurisdiction over the Foreign Defendants. MSPRC offers no more than bald assertions that Teva Pharmaceutical Industries, Emcure Ltd., Aurobindo Pharma, Ltd., and Alkem Laboratories Ltd., "on [their] own and/or through [their] subsidiaries regularly conduct[] business throughout the United States and its territories and possessions." FAC ¶¶ 29, 33, 44, 49. It does not specify what role the Foreign Defendants played in the manufacture of the allegedly contaminated MCDs, nor how they interacted with their U.S.-based counterparts to distribute and sell the MCDs at hand. MSPRC certainly has not alleged facts warranting piercing the corporate veil. Portfolio Fin. Servicing Co. ex rel. Jacom Comput. Servs., Inc. v. Sharemax.com, Inc., 334 F. Supp. 2d 620, 626 (D.N.J. 2004) ("Liability will not be imposed

[10] MSPRC does not offer a basis for personal jurisdiction over Emcure Ltd. or Alkem Laboratories, Ltd.

on the parent corporation merely because of its ownership of the subsidiary."). The Court therefore finds that it lacks personal jurisdiction as to the Foreign Defendants and dismisses the claims against them without prejudice.[11]

(2) Service

Moreover, even if personal jurisdiction existed over the Foreign Defendants, it is not clear that MSPRC properly effectuated service on Emcure Ltd., Alkem Laboratories, Ltd., or Aurobindo Pharma Ltd. under the Hague Convention on the Service Abroad of Judicial and Extra Judicial Documents in Civil or Commercial Matters (the "Hague Convention").[12]

The Hague Convention is an international treaty that principally governs service of process for foreign defendants. Celgene Corp. v. Distinct Pharma, No. 17-5303, 2018 WL 4251848, at *7 (D.N.J. Sept. 6, 2018). The Hague Convention authorizes several different mechanisms for effectuating international service of process, but the primary vehicle requires each participating country to set up a Central Authority for receiving and processing requests for service upon defendants residing within the state. See Hague Convention, Art. 2-7; Unite Nat'l Ret. Fund v. Ariela, Inc., 643 F. Supp. 2d 328, 333 (S.D.N.Y. 2008). Under this method, the party seeking to effect service must send a request for service directly to the Central Authority of the receiving

[11] The Court additionally finds that MSPRC has not presented sufficient allegations to meet the threshold showing to allow for jurisdictional discovery. Toys "R" Us, Inc. v. Step Two, S.A., 318 F.3d 446, 456 (3d Cir. 2003); Mass Sch. of Law at Andover, Inc. v. Am. Bar Ass'n, 107 F.3d 1026, 1042 (3d Cir. 1997) ("Our rule is generally that jurisdictional discovery should be allowed unless the plaintiff's claim is 'clearly frivolous.'"). MSPRC's conclusory statements regarding the Foreign Defendants' activities in New Jersey do not "suggest 'with reasonable particularity' the possible existence of the requisite 'contacts between [the Foreign Defendants] and the forum state,'" and the claim is clearly frivolous. Toys "R" Us, 318 F.3d at 456 (citation omitted); Mass Sch. of Law, 107 F.3d at 1042 ("[A] mere unsupported allegation that the defendant 'transacts business' in an area is 'clearly frivolous.'").

[12] Foreign Defendant Teva Pharmaceutical Industries Ltd. joined in the previous Motion to Dismiss, see ECF No. 105, and did not raise a defense for ineffective service. Therefore, the Court finds that Teva Pharmaceutical Industries Ltd. has waived that defense. See Fed. R. Civ. P. 12(h); Myers v. Am. Dental Ass'n, 695 F.2d 716, 721 (3d Cir. 1982) ("[The Rule 12(h) waiver rule] reflects a strong policy against tardily raising defenses that go not to the merits of the case but to the legal adequacy of the initial steps taken by the plaintiff in his litigation, namely his service of process on the defendant.").

country, which then serves the document or arranges for service by another agency. Hague Convention, Art. 2-5. The Central Authority must then complete a Certificate detailing how service was made or explaining why it did not occur, and this completed Certificate is returned to the applicant. Id. Art. 6.

Here, MSPRC has not informed the Court whether it received completed certificates from the relevant Central Authorities. Rather, MSPRC cites to cases where courts have declined to find improper service because a central authority has feigned non-service by its own failure to complete and return a certificate, but do not necessarily state that those facts are present here. Pl. Opp. at 101 n.31, ECF No. 134. Because MSPRC bear the burden of proving that service is valid, the Court finds that it has failed to demonstrate whether it properly served Emure Ltd., Alkem Laboratories, Ltd., and Aurobindo Pharma Ltd. under the Hague Convention. See Grand Entm't Grp. v. Star Media Sales, 988 F.2d 476, 488 (3d Cir. 1993) ("[T]he party asserting the validity of service bears the burden of proof on that issue.").[13]

C. Shotgun Pleading

Defendants next contend that MSPRC's claims should be dismissed under Federal Rule of Civil Procedure Rule 8(a)(2) because the FAC amounts to improper group pleading. The Court disagrees.

Rule 8(a)(2) requires a complaint to contain a "short and plain statement" of the allegations "in order to give the defendant fair notice of" the claims raised against them. Bell Atl. Corp., 550

[13] MSPRC maintains that even if service of an earlier complaint was improper, that is immaterial because it properly served the Foreign Defendants with the FAC. MSPRC provides no support for this contention and thus the Court has no way of evaluating the validity of this claim. See Rule 4(l)(1). Finally, as to MSPRC's claim that it still has time to serve the Foreign Defendants with the FAC, the Court will give MSPRC the opportunity to show that it has served them within thirty days of the Order accompanying this Opinion. To the extent MSPRC wishes to seek alternative methods of service, they must first show that they have exhausted the potential methods of service under the Hague Convention.

U.S. at 555 (internal citations omitted). "Complaints that violate this rule 'are often disparagingly referred to as shotgun pleadings.'" Abdul-Ahad v. Essex Cnty. Sheriff's Dep't, No. 15602, 2021 WL 4059835, at *4 (quoting Bartol v. Barrowclough, 251 F. Supp. 3d 855, 859 (E.D. Pa. 2017)). A pleading that does not "differentiate between defendants can warrant dismissal" under Rule 8(a) for failure to put Defendants on notice of their wrongdoing. Campbell v. City of New Brunswick, No. 165941, at *3 (D.N.J. May 16, 2018) (internal citations omitted).

The FAC is not a shotgun pleading. MSPRC alleges that each Defendant manufactured and sold contaminated MCDs, identifying each Manufacturer Defendant's failure to follow current Good Manufacturing Practices ("cGMPs"), specific warranties made by each Defendant, and identifying each Defendant who manufactured an MCD reimbursed by a TPP. FAC ¶¶ 27, 171-247; 272, 279-336. These allegations are therefore sufficient to put each Defendant on notice of the claims brought against it.

D. Preemption

Defendants next argue that MSPRC's state law claims[14] are preempted by federal law and are subject to the Primary Jurisdiction doctrine. Mfr. Def. Mem. at 26-38, Pharmacy Def. Mem. at 9-14. These arguments are unavailing.

The doctrine of preemption is rooted in the Supremacy Clause of the United States Constitution, which provides that the "Constitution, and the laws of the United States . . . shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2. Federal preemption arises under three circumstances: "(1) when a federal statute includes 'an express provision for preemption'; (2) '[w]hen Congress intends federal law to "occupy the field"' in an area of law, and (3) when a

[14] Defendants specifically seek to dismiss MSPRC's negligence per se, negligence, breach of express warranty, common law fraud, negligent misrepresentation, unjust enrichment, and state consumer protection claims as preempted by federal law. See Mfr. Def. Mem. at 26-38, Pharmacy Def. Mem. at 9-14.

state and federal statute are in conflict." In re Fosamax (Alendronate Sodium) Prod. Liab. Litig. (No II), 751 F.3d 150, 158-59 (3d Cir. 2014) (quoting Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 372 (2000)). Preemption is an affirmative defense and the burden of proof is on the defendant. Lupian v. Joseph Cory Holdings LLC, 905 F.3d 127, 130 (3d Cir. 2018). "The question of whether a certain state action is pre-empted by federal law is one of congressional intent." Gade v. Nat'l Solid Wates Mgmt. Ass'n, 505 U.S. 88, 96 (1992) (internal citation omitted).

1. FDCA

Defendants rely on a theory of implied preemption articulated by the Supreme Court in Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2000). There, the Court held that state law claims are preempted where they "exist solely by the virtue of the [Federal Drug and Cosmetics Act ("FDCA")]." Id. at 353. The Court relied on the Food and Drug Administration's ("FDA") statutory and regulatory framework as aiming to achieve a "delicate balance of statutory objectives," which could be skewed by attempts to enforce FDA requirements through state common law. Id. at 348. Applying Buckman, the Manufacturer Defendants contend that MSPRC's claims depend on proving a violation of the FDCA, such as non-compliance with cGMPs, violating the FDA's duty of sameness,[15] or violating the FDA's prohibition on mixing a drug with a substance that reduces its quality.[16]

However, a fair reading of the FAC demonstrates that MSPRC's state law claims do not "arise solely from" FDCA requirements, but are also based on independent state law duties. For

[15] See 21 U.S.C. § 351(b)(1) (providing that a drug is adulterated "[i]f it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium.").

[16] See 21 U.S.C. § 351(d) (providing that a drug is adulterated if "any substance has been (1) mixed or packaged therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.").

example, under New Jersey law, a claim for breach of express warranty requires: "(1) that [a d]efendant made an affirmation, promise or description about the product; (2) that this affirmation or description became part of the basis of the bargain for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description." Snyder v. Farnam Cos., Inc., 792 F. Supp. 2d 712, 721 (D.N.J. 2011); N.J.S.A. § 12A:2-313. MSPRC alleges that the Manufacturer Defendants expressly warranted that their products were fit for ordinary consumption but breached that warranty by manufacturing contaminated MCDs. FAC ¶¶ 370-72. MSPRC's claims are based on state law and contract duties to refrain from breaching warranties, which exist independently of FDA regulations. See In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig., No. 2875, 2020 WL 7418006, at *54 (D.N.J. Dec. 17, 2020) (finding that plaintiffs' negligence per se, strict liability, breach of express warranty, fraud, and state consumer protection claims were not preempted by the FDCA because "Plaintiffs' claims depend on traditional tort and contract law sources").

Moreover, Buckman's application "is often limited to 'fraud-on-the-agency' claims[17] and not extended to claims based on state law tort principles." Mendez v. Shah, 28 F. Supp. 3d 282, 291 (D.N.J. 2014) (internal quotation omitted); see also Freed v. St. Jude Med., Inc., 364 F. Supp. 3d 343, 352 (D. Del. 2019) ("To avoid implied preemption under Buckman, a claim must assert violation of a state tort duty that also violates some FDA requirement."); Bull v. St. Jude Med., Inc., No. 17-1141, 2018 WL 3397544, at *27 (E.D. Pa. July 12, 2018) ("State law claims that allege liability based on a common law tort theory and which parallel federal law claims . . . are not impliedly preempted under Buckman."). Because MSPRC's claims rely "on traditional state

[17] In Buckman, the Court referred to claims as "fraud-on-the-FDA" claims where plaintiffs brought state-law causes of action to assert that an entity made fraudulent representations to the FDA, resulting in improper regulatory approval of medical devices. 531 U.S. at 347. Such claims are absent here.

tort law which . . . predated the federal enactments in question," they are not preempted by the FDCA. Buckman, 531 U.S. at 353.

2. Primary Jurisdiction Doctrine

The Manufacturer Defendants additionally assert that the Court should dismiss or abstain from deciding all of MSPRC's claims under the primary jurisdiction doctrine in deference to the FDA's expertise. The Court disagrees, finding that review of the relevant factors weighs against applying the doctrine.

The primary jurisdiction doctrine allows a court to stay a proceeding or dismiss a complaint without prejudice pending the resolution of an issue that is within the special competence of an administrative agency. Robles v. Domino's Pizza, LLC, 913 F.3d 898, 909-10 (9th Cir. 2019). To determine whether to apply the doctrine of primary jurisdiction, Courts apply a four-factor test, analyzing:

> (1) Whether the question at issue is within the conventional expertise of judges or whether it involves technical or policy considerations within the agency's particular field of expertise; (2) Whether the question at issue is particularly within the agency's discretion; (3) Whether there exists a substantial danger of inconsistent rulings; and (4) Whether a prior application to the agency has been made.

Raritan Baykeeper v. NL Indus., 660 F.3d 686, 691 (3d Cir. 2011) (quoting Global Naps, Inc. v. Bell Atl.-N.J., 287 F. Supp. 2d 532, 549 (D.N.J. 2003)). "Abstention . . . is the exception rather than the rule." Id. (internal citation omitted).

The first factor "focuses on the competence of the court and the agency to address the matter." Id. The Manufacturer Defendants contend that MSPRC's allegations require investigation into technical issues delegated to the FDA's expertise, including whether Defendants' MCDs are bioequivalent to the RLDs and are manufactured in accordance with

cGMPs. Mfr. Def. Mem. at 35. However, the FDA has already determined that Defendants' MCDs were contaminated with NDMA, see FAC ¶¶ 272-73, making "the Court's starting point as to the [MCDs'] lack of chemical bioequivalence plain and simple."[18] In re Valsartan, 2020 WL 7418006, at *62; see also Endo Pharms. Inc. v. Actavis Inc., 592 F. App'x 131, 134 (3d Cir. 2014) ("Now that the FDA has issued its determination, . . . the District Court's rationale for applying the primary jurisdiction doctrine is moot."). Furthermore, the Court's review of expert reports as to whether the Defendants complied with cGMPs or its general duties of care do not stray beyond the Court's normal range of competence in products liability actions. As "the matter is not one peculiarly within the agency's area of expertise, but is one which the courts and jury are equally well-suited to determine, the court must not abdicate its responsibility." Raritan Baykeeper, 660 F.3d at 691.

The second factor also weighs against the application of primary jurisdiction. Although drug regulation is within the realm of the FDA's expertise, broader concerns about the misrepresentation of the contents of a particular drug have not been found to be particularly within the FDA's discretion. See, e.g., In re Valsartan, 2020 WL 7418006, at *63 (finding that the FDA "does not and cannot attest to its particular . . . discretion over the presence of these contaminants . . . in the U.S. drug supply" (alteration in original)). Further, because the questions at issue mainly involve state tort law, the "question[s] at issue" here are not particularly in the discretion of the FDA. In re Methyl Tertiary Butyl Ether Prods. Liab. Litig., 175 F. Supp. 2d 593, 618 (S.D.N.Y. 2001) ("[C]ourts generally invoke the primary jurisdiction doctrine where a specific issue raised

[18] The Manufacturer Defendants contest this point, proffering FDA reports to show that no such NDMA was detected in its products. Mfr. Def. Mem. at 37. However, at the motion to dismiss stage, the Court will only consider the four corners of the complaint, documents integral to the complaint, and "any undisputedly authentic document that a defendant attaches . . . if the plaintiff's claims are based on the document." Schuchardt v. President of the U.S., 839 F.3d 336, 353 (3d Cir. 2016) (quoting In re Asbestos Prods. Liab. Litig., 822 F.3d 125, 133 & n.7 (3d Cir. 2016)).

is 'squarely placed within [the agency's] informed expert discretion and the agency being deferred to is capable of deciding the issue." (alteration in original) (internal quotation omitted)).

With respect to the third factor, the Manufacturer Defendants argue that MSPRC's claims require the Court to adjudicate whether Defendants' MCDs contain NDMA and/or whether Defendants have complied with federal regulatory requirements. Mfr. Def. Mem. at 36. However, the specific relief sought by MSPRC, namely money damages for the TPP's economic losses, is not provided by the FDA and "courts generally do not defer jurisdiction where plaintiffs seek damages for injuries to their property or person." In re Methyl Tertiary Butyl Ether Prods. Liab. Litig., 175 F. Supp. 2d at 618 (citing Friends of Santa Fe Cnty. v. Lac Minerals, 892 F. Supp. 1333, 1350 (D.N.M. 1995)). Thus, there is little danger of inconsistent rulings here.

Fourth and finally, while the Manufacturer Defendants assert that the FDA is continuing to investigate impurities in MCDs, Mfr. Def. Mem. at 37, MSPRC has not made prior applications to the FDA. While this factor favors abstention, "this single factor cannot outweigh the others that disfavor abstention on primary jurisdiction grounds." Raritan Baykeeper, 660 F.3d at 692; cf. Global Naps, 287 F. Supp. 2d at 549 (finding abstention appropriate where the plaintiff made a prior application to the relevant agency). Therefore, the Court declines to dismiss or abstain on the basis of primary jurisdiction.[19]

E. Subsumption

The Manufacturer Defendants next argue that MSPRC's breach of implied warranty, unjust enrichment, negligence, and negligence per se claims are subsumed by the New Jersey Products Liability Act ("PLA"), N.J.S.A. §§ 2A:58C-1, et seq. Mfr. Def. Mem. at 38-41. MSPRC counters

[19] As the Court already found that the Consumer Plaintiffs lack standing, and thus no claims against the Pharmacy Defendants remain, it need not reach the issue of whether the Drug Supply Chain Security Act preempts the claims against the Pharmacy Defendants.

that the PLA does not apply to their theory of liability. Pl. Opp. at 43, ECF No. 134. The Court agrees with MSPRC.

The PLA was intended to limit the expansion of products-liability law and "the liability of manufacturers so as to balance[] the interests of the public and the individual with a view towards economic reality." Tawil v. Ill. Tool Works, Inc., No. 15-8747, 2016 WL 4260791, at *6 (D.N.J. Aug. 11, 2016) (alteration in original) (quoting Zaza v. Marquess & Nell, Inc., 144 N.J. 34, 47-48 (1996)). The PLA provides an exclusive cause of action, thereby subsuming all claims falling under its purview. Estate of Knoster v. Ford Motor Co., 200 F. App'x 106, 115 (3d Cir. 2006). The Act defines a "product liability action" as "any claim or action . . . for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty." N.J.S.A. § 2A:58C-1(b) (emphasis added). Moreover, claims for physical damage to the product itself are not considered products liability actions "because the PLA specifically excludes such damage from its definition of 'harm.'" Estate of Knoster, 200 F. App'x at 116 (citing N.J.S.A. § 2A:58C-1(b)(2), (3)). To determine whether a claim is subsumed by the PLA, courts look at whether the claim is based upon a product's manufacturing, warning, or design defect and is therefore covered by the PLA. See Sun Chem. Corp. v. Fike Corp., 981 F.3d 231, 237 (3d Cir. 2020).

MSPRC seeks to recover for the loss the TPPs incurred by paying for a product that allegedly had no value. See FAC ¶¶ 1, 6-11, 27. As the Court recently recounted in In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig., MDL No. 2875, 2021 WL 364663, at *49 (D.N.J. Feb. 3, 2021), "claims alleging that a plaintiff 'did not get what [they] paid for' are not subsumed by the PLA." (quoting Gorczynski v. Electrolux Home Prods., Inc., No. 18-10661, 2019 WL 5304085, at *3 (D.N.J. Oct. 18, 2019)). While the Manufacturer Defendants assert that the heart

of MSPRC's case is the potential for harm caused by the MCDs, Mfr. Def. Rep. at 15, ECF No. 139, this Court has rejected similar arguments in cases where there is alleged harm to the product itself, there are no allegations of physical harm, and the parties do not seek damages for physical harm. See, e.g., Volin v. G.E., 189 F. Supp. 3d 411, 418 (D.N.J. 2016) (finding that claims of defective microwave knobs were not subsumed by the PLA because the defect diminished the value and usefulness of the microwaves and established only "harm to the product itself."); Gorcynzki, 2019 WL 5304085, at *10 (holding that claims for defectively hot microwaves were not subsumed by the PLA because the claims "relate[] exclusively to economic damages resulting from harm to the product itself"). At this stage, the Court finds that MSPRC's claims, as alleged, are not subsumed by the PLA.

F. Rule 12(b)(6) Failure to State a Claim

Defendants next argue that the FAC should be dismissed because MSPRC has failed to plead essential elements of each claim. Mfr. Def. Mem. at 41-64, Pharmacy Def. Mem. at 15-40. The Court agrees in part with Defendants and addresses each claim in turn[20].

1. Breach of Express Warranty (Count Two)

Defendants first challenge the adequacy of MSPRC's pleadings for its claims of breach of express warranty, maintaining that MSPRC failed to allege how any specific warranty language

[20] The parties have not briefed the issue of choice of law, but because this is a diversity case, the Court applies New Jersey choice-of-law rules, see Gay v. Creditinform, 511 F.3d 369, 389 (3d Cir. 2007). Under these rules, "New Jersey courts apply the two-pronged 'most significant relationship' test of the Restatement (Second) of Conflict of Laws." Curtiss-Wright Corp. v. Rodney Hunt Co., 1 F. Supp. 3d 277, 283 (D.N.J. 2014) (citing P.V. v. Camp Jaycee, 197 N.J. 132 (N.J. 2008)). First, the Court must "determine whether an actual conflict exists" between the law of the states with an interest in the claim. P.V., 197 N.J. at 143. Next, if no conflict exists, a court may "refer interchangeably to the laws of [relevant states] in discussing the law applicable to the case." On Air Ent. Corp. v. Nat'l Indem. Co., 210 F.3d 146, 149 (3d Cir. 2000). If a conflict does exist, step two requires courts to "determine which jurisdiction has the 'most significant relationship' to the claim. Curtiss-Wright Corp., 1 F. Supp. 3d at 283 (citing P.V., 962 A.2d 453).

The parties here appear to agree that where there is a conflict, the law of the state where a particular transaction took place govern, and the Court assumes without deciding that that is the case. The Court will only apply the laws of

formed the basis of a bargain between MSPRC and Defendants. Mfr. Def. Mem. at 45-46, Pharmacy Def. Mem. at 16-17. These arguments are unavailing.

Under New Jersey law, "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." N.J.S.A. § 12A:2-313(1)(a). Failure to point to specific warranty language in pleading a breach of express warranty claim warrants dismissal under Rule 12(b)(6). See, e.g., Garten v. Intamin Amusement Rides Int. Corp. Est., No. 19-20040, 2021 WL 1976701, at *14 (D.N.J. May 18, 2021) (dismissing breach of express warranty claim where plaintiff did not "point to any actual warranty language"); Simmons v. Stryker Corp., No. 08-3451, 2008 WL 4936982, at *2 (D.N.J. Nov. 17, 2008) (dismissing claim because it was "devoid of any 'factual matter' to support the existence of an express warranty"). With respect to the "basis of the bargain" element, a plaintiff must allege that they "read, heard, saw or knew of" the express warranty "when choosing to use the product." Greisberg v. Boston Sci. Corp., No. 19-12646, 2020 WL 4435409, at *5 (D.N.J. Aug. 3, 2020).

MSPRC has sufficiently pled the specific language of the express warranties at issue, namely the labeling and product name which "represent and warrant to end-users and TPPs that their MCDs are in fact the same as and are therapeutically interchangeable with their RLDs." See FAC ¶ 283; see also In re Valsartan III, 2021 WL 222776, at *60 ("[B]ecause of the economic reality of drug sales in the U.S., the [manufacturer]'s identification of a generic drug as the chemical equivalent to the Orange Book[21] brand name can do nothing else but constitute an express

states other than New Jersey to the extent that Defendants have identified a specific conflict. Of course, nothing in this Opinion prevents either party from raising additional conflict of law concerns on a future Motion to Dismiss or on a full record following discovery.

[21] The Orange Book is a list maintained by the FDA of "Approved Drug Products with Therapeutic Equivalence Evaluations." FAC ¶ 280.

warranty."). The FAC further alleges that the TPPs relied on the Manufacturer Defendants' warranties that the MCDs were as they were labeled to be. FAC ¶ 283. In In re Valsartan III, this Court held that very similar facts constituted sufficient allegations to show that a warranty had formed the basis of a bargain:

> The [manufacturers'] very naming of the drug of valsartan or valsartan-containing [drug] amounted to an express warranty on which plaintiffs had no choice but to "rely" when they were prescribed the drug and bought it as a medication for their high blood pressure. Plaintiffs did not have to "perceive" the package labelling or insert in order to create the benefit of the bargain. All they had to know was they were buying a generic drug that contained valsartan because the very name "valsartan" or "valsartan-containing" constituted itself an express warranty that what plaintiffs were purchasing was the chemical equivalent of the Orange Book pharmaceutical.

2021 WL 222776, at *62. The same logic applies here, and the Court finds that MSPRC has sufficiently pleaded its express warranty claims.[22]

[22] Defendants Actavis Pharma, Inc., Actavis LLC, Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Ltd. ask the Court to rely on a recent non-binding decision in Harris v. Pfizer Inc., No. 21-6789, 2022 WL 488410 (S.D.N.Y. Feb. 16, 2022), in which the court found that allegations that a brand name drug was contaminated with a possibly carcinogenic compound were insufficient to sustain claims for fraud, negligent misrepresentation, breach of express warranty, breach of implied warranty, violations of state consumer fraud laws, and unjust enrichment. See ECF No. 150. In particular, the Harris court focused on the lack of false or misleading representations, stating that "neither the product label nor the medication guide state that varenicline is the only biologically active ingredient in Chantix. And presence of a contaminant does not render the brand name on the label false – contaminated Chantix is still Chantix." Id. at *9. However, the court distinguished the case from one like In re Valsartan, noting that "Chantix is a brand name drug. Its name therefore confers no warranty that it is identical to anything except itself." Id. at *19.

MSPRC's claims here center only on generic drugs, outlining the generic drug approval process and the requirement that generic drugs must demonstrate bioequivalence to the RLD. FAC ¶¶ 109-12. MSPRC has sufficiently alleged that the labeling of a generic drug confers a warranty that there is the "absence of significant difference," such that contamination of a generic drug would constitute a breach of warranty. See id. ¶ 112 (quoting 21 C.F.R. § 320i(e)). Accordingly, Harris does not change the present analysis.

2. Breach of Implied Warranty of Merchantability (Count Four)

(1) New Jersey & Indiana Law

The Manufacturer Defendants next assert that MSPRC's breach of implied warranty claims fail under New Jersey and Indiana law because it does not allege how any defect impaired the product's functionality or caused an injury. In other words, they maintain that merely alleging that a defect or impurity existed is insufficient to sustain a breach of implied warranty claim under New Jersey and Indiana Law. Mfr. Def. Mem. at 42. This argument is unavailing.

Both New Jersey and Indiana have adopted Section 2-314 of the Uniform Commercial Code, which requires that a plaintiff allege (1) that a merchant sold goods; (2) the goods were not "merchantable" at the time of sale; (3) injury and damages to the plaintiff or its property; and (4) which were caused proximately and in fact by the defective nature of the goods. See N.J.S.A. § 12A:2-314; Ind. Code § 26-1-2-314; In re Ford Motor Co. E-350 Van Prods. Liab. Litig., No. 03-4558, 2008 WL (D.N.J. Sept. 3, 2008). MSRPC has alleged that its TPPs made payments for MCDs that were contaminated with NDMA, and that as a result of that contamination, the drugs were economically worthless and caused economic damages. FAC ¶¶ 27, 394-96.

As a court in this District recently held, "contaminated drugs, even if medically efficacious for their purpose, cannot create a benefit of the bargain because the contaminants, and their dangerous effects, were never bargained for." In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig. (In re Valsartan III), MDL No. 2875, 2021 WL 222776, at *74 (D.N.J. Jan. 22, 2021). The fact that MSPRC alleges that the contamination caused the drug to be economically worthless sufficiently distinguishes this case from those the Manufacturing Defendants cite to, in which there were no allegations of injury. Cf. Hoffman v. Nutraceutical Corp., No. 12-5803, 2013 WL 2650611, at *12 (D.N.J. June 10, 2013) (dismissing breach of implied warranty claim where

"Plaintiff merely asserts that some of Defendant's product contained 1.7 micrograms of lead"); Bowman v. RAM Med. Inc., No. 10-4403, 2012 WL 1964452, at *15 (D.N.J. May 31, 2012) ("Plaintiffs do not supply any supporting facts . . . rendering the product valueless or unfit."). Moreover, Defendants cite no legal authority for the contention that MSPRC must allege a physical injury or that the MCDs lack any therapeutic benefit to successfully state a claim for breach of implied warranty. Accordingly, the Court denies the Manufacturer Defendants' motion on this Count.

(2) California & New York Law

The Manufacturer Defendants make similar arguments under California and New York law. Specifically, they assert that to state a claim for breach of the implied warranty of merchantability in California, MSPRC must allege a fundamental defect that renders the product unfit for its ordinary purpose, as well as vertical privity under the Song-Beverly Act, Cal. Civ. Code § 1790, et seq. Mfr. Def. Mem. at 43-44. The Manufacturer Defendants further argue that MSPRC's implied warrant claim under New York law fails because there is no privity between the manufacturer and the TPPs. Id. at 44. The Court agrees in part.

First, as discussed supra, MSPRC has sufficiently alleged that the NDMA contamination rendered the MCDs unfit for their ordinary purpose. As to privity under California law, "the weight of authority [shows] that the plain language of section 1792 of the Song-Beverly Act does not impose a . . . vertical privity requirement." Thorton v. Micro-Star Int'l Co., No. 17-3231, 2018 WL 5291925, at *35 (C.D. Cal. Oct. 23, 2018); see also Ehrlich v. BMW of N. Am., LLC, 801 F. Supp. 2d 908, 921 (C.D. Cal. 2010) (listing cases that have found privity unnecessary for a Song-Beverly implied warranty claim). Thus, MSPRC has sufficiently stated a claim for breach of implied warranty under California law.

By contrast, New York law does require vertical privity where no personal injury is alleged. See, e.g., Hole v. General Motors Corp, 442 N.Y.S.2d 638, 640 (N.Y. App. Div. 1981) (holding that New York law "does not permit a plaintiff, not in privity, to recover upon the breach of an implied warranty of merchantability unless the claim of the remote user is for personal injuries"). MSPRC cites to a singular case, Addeo v. Metro. Bottling Co., 241 N.Y.S.2d 120 (N.Y. App. Div. 1963), to argue that this case falls under a foodstuffs and pharmaceuticals exception to the vertical privity requirement. Pl. Opp. at 53, ECF No. 134. However, Addeo predates New York's enactment of the UCC, and no such exception to the privity requirement exists under present New York law. See Weisblum v. Prophase Labs, Inc., 88 F. Supp. 3d 283, 296 (S.D.N.Y. 2015). Because MSPRC has not alleged privity between the TPPs and the Manufacturer Defendants, MSPRC's claims for breach of implied warranty under New York law are dismissed.

3. Magnuson-Moss Warranty Act (Count Six)

Defendants next argue for dismissal of MSPRC's claims under the MMWA, 15 U.S.C. §§ 2301-2312, contending that (1) the MMWA is inapplicable to MCDs because federal law controls the content of a generic drug's label; and (2) Plaintiffs did not meet the pleading requirements of the MMWA because they failed to present to any defendant that the drug was contaminated and seek a "repair." MSPRC does not dispute these points, and the Court finds that the MMWA claims warrant dismissal.

The MMWA provides a private cause of action in federal court for consumers who are "damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation . . . under a written warranty, [or] implied warranty." 15 U.S.C. § 2310(d)(1). A claim under the MMWA is coextensive with underlying state implied and express warranty claims. See Cooper v. Samsung Elecs. Am., Inc., 374 F. App'x 250, 254 (3d Cir. 2010). To plead a violation

under the MMWA, a plaintiff must assert (1) a valid warranty; (2) the product was presented for repair during the warranty period; and (3) the manufacturer failed to repair the product to warranty standards within a reasonable amount of time or number of attempted repairs. In re Valsartan III, 2021 WL 222776, at *84. MSPRC has made no allegations that the TPPs presented their contaminated MCDs to Defendants for repair.

Furthermore, the MMWA is "inapplicable to any written warranty the making or content of which is otherwise governed by Federal law." 15 U.S.C. 2311(d). This Court has recently endorsed the view that this provision prohibits MMWA warranty claims involving FDA-regulated items. See, e.g., In re Valsartan III, 2021 WL 222776, at *84-86 (dismissing MMWA claims relating to medication because the drugs were regulated by the FDA); Hernandez v. Johnson & Johnson Consumer, Inc., No. 19-15679, 2020 WL 2537633, at *5 (D.N.J. May 19, 2020) (same); Dopico v. IMS Trading Corp., No. 14-1874, 2018 WL 4489677 (D.N.J. Sept. 18, 2018) (dismissing claims involving pet food because it was regulated by the FDA). Therefore, the TPP's MCDs are not proper subjects for an MMWA claim and the Court accordingly grants Defendants' motions as to Count Six.

4. Common Law Fraud (Count Eight) [23]

Defendants next argue that MSPRC's common law fraud claims fail to satisfy the applicable "heightened specificity requirements" of Federal Rule of Civil Procedure 9(b). The Court agrees.

[23] As a preliminary matter, the Manufacturing Defendants unpersuasively contend that MSPRC's fraud-based claims, including their state consumer fraud and negligent misrepresentation claims, are time barred. Mfr. Def. at 50-51. A "statute of limitations is an affirmative defense, and the burden of establishing its applicability to a particular claim rests with the" party asserting the defense. Drennan v. PNC Bank, NA (In re Comty. Bank of N. Va. & Guaranty Nat'l Bank of Tallahassee, 622 F.3d 275, 292 (3d Cir. 2010) (citation omitted). MSPRC alleges that their causes of action accrued in June 2020 with the FDA announcement of Defendants' recalls, and they filed their original complaint in July 2020. FAC ¶ 337, ECF No. 1. Defendants do not proffer any support for their position that MSPRC's claims

Rule 9(b) provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." To satisfy this requirement, a plaintiff must provide "precise allegations of date, place or time" in its pleading or use other "means of injecting precision and some measure of substantiation into [its] allegations of fraud." Bd. of Trs. of Teamsters Loc. 863 Pension Fund v. Foodtown, Inc., 296 F.3d 164, 172 n.10 (3d Cir. 2002) (internal quotation omitted). This standard is intended "to place the defendants on notice of the precise misconduct with which they are charged . . . ." Lum v. Bank of Am., 361 F.3d 217, 223-24 (3d Cir. 2004). While there is some variation across state fraud laws, the basic elements consistently require that a plaintiff prove (1) the defendant made a materially false representation; (2) knowledge of the falsity or reckless indifference as to the falsity; (3) intent to deceive; (4) the plaintiff acted in reliance on the representation; and (5) damages as a result of the reliance. See, e.g., Allstate N.J. Ins. Co. v. Lajara, 222 N.J. 129, 147 (2015); Lazar v. Super. Ct. (Rykoff-Sexton, Inc.), 909 P.2d 981 (Cal. 1996); Schmidt v. Mel Clayton Ford, 124 Ariz. 65, 67 (Ariz Ct. App. 1979); Stephenson v. Capario Dev. Co., 462 A.2d 1069, 1073 (Del. 1983).

As an initial matter, the Court disagrees that MSPRC has failed to particularly allege a misrepresentation to sustain its claims sounding in fraud. Specifically, it has alleged the exact misrepresentations the Manufacturing Defendants allegedly made—namely that the MCDs were bioequivalent to their RLDs and that the defendants followed cGMPs. See In re Valsartan III, 2021 WL 222776, at *60-64 (finding a fraud claim adequately alleged where manufacturing defendants misrepresented that a drug was therapeutically equivalent to its RLD, that it complied with cGMPs, and was unadulterated and properly branded, and that these representations were

accrued prior to that time and thus do not bear their burden of establishing that the claims are barred by the applicable statute of limitations.

false because the presence of contaminants rendered the drugs non-bioequivalent to the RLD). MSPRC points to specific representations made by the Manufacturer Defendants on their websites, stating that their drugs are made in accordance to cGMPs and are equivalent to Metformin, which suffices to show that the defendants made materially false statements. See, e.g., FAC ¶¶ 295-303 (quoting alleged representations from Defendant Teva Pharmaceutical Industries USA's website that state that its MCDs were bioequivalent to its RLDs and that it complied with cGMPs).

However, the Court agrees with Defendants that MSPRC's allegations do not adequately plead the element of knowledge. All states require fraud claims to allege an element of scienter involving actual knowledge or, at a minimum, reckless ignorance of the falsity of a misrepresentation. See, e.g., Maertin v. Armstrong World Indus, 241 F. Supp. 2d 434, 459 (D.N.J. 2002) (citing Gennari v. Weichert Co. Realtors, 148 N.J. 582, 691 (1997)) (requiring "knowledge or belief by the defendant of its falsity"); Bilimoria Comput. Sys. v. Am. Online, Inc., 829 N.E.2d 150, 155 (Ind. Ct. App. 2005) (quoting Wallem v. CLS Indus., Inc., 725 N.E. 2d 880, 889 (ind. Ct. App. 2000) (requiring a false material representation that "was made with knowledge or reckless ignorance of its falsity"). Because this information is often in the exclusive control of a defendant, circumstantial evidence is sufficient to meet Rule 9(b)'s pleading standard for this element. See Caspersen as Tr. for Samuel M.W. Caspersen Dynasty Tr. v. Oring, 441 F. Supp. 3d 23, 40 (D.N.J. 2020) ("Rule 9(b) expressly provides that "[m]alice, intent knowledge and other conditions of a person's mind may be alleged generally" (alteration in original)).

While MSPRC has adequately alleged that the Manufacturing Defendants made a materially false representation—that the MCDs were unadulterated and therapeutically equivalent to their RLDs—it has failed to allege any facts to show that the Defendants had knowledge or were reckless as to the falsity of those representations. The FAC alleges that each Manufacturer

Defendant had factories subject of FDA investigations that found cGMPs violations. FAC ¶¶ 173-247. However, MSPRC only identifies two of those factories as responsible for manufacturing Defendants' MCDs, and do not specify whether Defendants produced any significant percentage of its MCDs at those factories. From these allegations, the Court could plausibly infer only that a minor percentage of MCDs were manufactured in these problematic facilities, which does not suffice to show that Defendants were reckless as to the quality controls involved in producing all their MCDs or those specifically paid for by the TPPs.

Moreover, MSPRC has certainly failed to allege any facts to show that the Manufacturing Defendants had knowledge of the contaminated MCDs. Despite MSPRC's reliance on In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig. (In re Valsartan IV), MDL No. 2875, 2021 WL 307486 (D.N.J. Jan. 29, 2021), MSPRC here has made far fewer allegations as to Defendants' state of mind. Pl. Opp. at 67-68. Specifically, in In re Valsartan IV, the plaintiffs alleged that the manufacturer defendants manipulated testing and "evolved its fraudulent methods to evade detection" by the FDA. 2021 WL 307486, at *43. MSPRC makes no such allegations of consciousness of guilt, but merely make bald assertions that the Manufacturer Defendants had knowledge of the NDMA contamination. See Hemy v. Perdue Farms, Inc., No. 11-888, 2011 WL 6002463, at *13 (D.N.J. Nov. 30, 2011) ("A complaint must do more than assert generalized facts, it must allege facts specific to the plaintiff."). The Court therefore grants the Defendants' Motions as to Count Eight.[24]

[24] As the requirements for fraud vary from state to state, any renewed Motion to Dismiss must break down its arguments on which elements are lacking under the laws of each state.

5. Negligent Misrepresentation (Count Ten)

The Manufacturing Defendants next challenge whether MSPRC has adequately alleged the requisite elements for negligent misrepresentation. Mfr. Def. at 53-54. MSPRC does not dispute this argument, and the Court agrees with Defendants that MSPRC has failed to state a claim for negligent misrepresentation.

Although the exact requirements vary from state to state, to plead negligent misrepresentation, a plaintiff generally must allege (1) a special relationship imposing a duty on the defendant to impart correct information to a plaintiff; (2) that the information was false; and (3) there was reasonable reliance on the information. See, e.g., Alexander v. CIGNA Corp., 991 F. Supp. 427, 440 (D.N.J. 1998) (citing H. Rosenblum, Inc. v. Adler, 93 N.J. 324 (N.J. 1983)) Mandarin Trading Ltd. Wildenstein, 16 N.Y.3d 173, 180 (N.Y. Ct. App. 2011); Elchos v. Haas, 178 So. 3d 1183, 1197 (Miss. 2015); Bock v. Hansen, 225 Cal. App. 4th 215 (Cal. App. 2014); Bilt-Rite Contrs., Inc. v. Architectural Studio, 581 Pa. 454, 466 (Pa. 2002).

MSPRC has failed to allege any special relationship or duty to disclose that obligated the Defendants to inform the TPPs of contamination. See Hartman v. Wells Fargo Bank, N.A. (In re Hartman), No. 15-7093, 2017 WL 2230336, at *8 (D.N.J. May 22, 2017) ("If there is no duty owed to a plaintiff independent of what the defendant owes plaintiff under a contract, a plaintiff may not maintain a tort claim (as a necessary element of the tort claim is absent)." (quoting S. Broward Hosp. Dist. v. MedQuist, Inc., No. 05-2206, 516 F. Supp. 2d 370, 396 (D.N.J. 2007))); Prime Mover Capital Partners, L.P. v. Elixer Gaming Techs., Inc., 793 F. Supp. 2d 651, 673-74 (S.D.N.Y. 2011) ("[U]nder New York law, a plaintiff may recover for negligent misrepresentation only where the defendant owes her a fiduciary duty."); Premier Bus. Grp., LLC v. Red Bull of N. Am., Inc., No. 08-1453, 2009 WL 3242050, at *11 (N.D. Ohio Sept. 30, 2009) ("[N]egligent

misrepresentation requires a special relationship under which the defendant supplied information to the plaintiff for the latter's guidance in its business transactions.") (internal quotations omitted). MSPRC has not alleged any facts to show that Defendants owed the TPPs an independent legal duty, or that there was a privity relationship between the TPPs and the Manufacturer Defendants. Indeed, "there is no general duty to disclose to the entire world." In re Am. Med. Collection Agency Customer Data Sec. Breach Litig., No. 19-2904, 2021 WL 5937742, at *80 (D.N.J. Dec. 16, 2021) (internal quotation marks omitted). The Court therefore grants the Manufacturer Defendants' Motion as to Count Ten.[25]

6. State Consumer Protection Laws (Counts Twelve & Twenty)

The Manufacturing Defendants subsequently argue that MSPRC's state consumer protection law claims fail under the laws of California, Indiana, New Jersey, and New York. Mfr. Def. Mem. at 54-58. The Court agrees in part and addresses each state claim individually.

(1) California

Defendants dispute whether MSPRC has adequately alleged claims under California's Unfair Competition Law ("UCL"), Cal. Bus & Prof. Code §§ 17200, et seq., False Advertising Law ("FAL"), Cal. Bus & Prof. Code §§ 17500, et seq., and Consumers Legal Remedies Act ("CLRA"), Cal. Civ. Code §§ 1770, et seq.[26] Specifically, the Manufacturing Defendants contend that MSPRC must plead actual knowledge of falsity to sustain their claims under California law.

[25] As with the fraud claims, because there is so much variation between states on the applicable requirements to state a claim for negligent misrepresentation, any future Motions to Dismiss must specify how MSPRC's claims fail under each state law.

[26] The Court rejects the Manufacturing Defendants' argument that MSPRC has failed to allege an injury in fact or damages, as this Court has already found both to be pled. See supra Section IV.A.

The UCL "covers a wide range of conduct," including unlawful, unfair, and fraudulent business practices. Korea Supply Co. v. Lockheed Martin Corp., 29 Cal. 4th 1134, 1143 (Cal. 2003). "An act can be alleged to violate any or all of the three prongs of the UCL—unlawful, unfair, or fraudulent." Berryman v. Merit Prop. Mgmt., Inc., 152 Cal. App. 4th 1544, 1554 (Cal. App. 2007). A claim under the unlawful prong of the UCL "rises or falls with the underlying claim," meaning a UCL cause of action under this prong fails if a statutory predicate is not stated. Upper Deck Co. v. Panini Am., Inc., 533 F. Supp. 3d 956, 968 (S.D. Cal. 2021); see also Aleksick v. 7-Eleven, Inc., 205 Cal. App. 4th 1176, 1185 (Cal. App. 2012). "Virtually any statute or regulation (federal or state) can serve as a predicate for a UCL unlawful practice cause of action." Gutierrez v. Carmax Auto Superstores Cal., 19 Cal. App. 5th 1234, 1265 (Cal. App. 2018). An act or practice is unfair under the UCL "if the consumer injury is substantial, is not outweighed by any countervailing benefits to consumers or to competition, and is not an injury the consumers themselves could reasonably have avoided." Daugherty v. Am. Honda Motor Co., Inc., 144 Cal. App. 4th 824, 839 (Cal. App. 2006). Finally, under the "fraudulent" prong, a plaintiff must allege that members of the public are likely to be deceived by a fraudulent business act or practice and that there was an affirmative duty to disclose. Id. at 838.

MSPRC alleges that their UCL claims are based in part on violations of the CLRA and FAL. The CLRA prohibits "unfair methods of competition and unfair or deceptive acts or practices." Cal. Civ. Code § 1770(a). The FAL makes it unlawful to induce the public to enter into any obligation through the dissemination of "untrue or misleading" statements. Cal. Bus. & Prof. Code § 17500. As the CLRA, FAL, and the fraudulent prong of the UCL all sound in fraud, courts routinely analyze claims under all three statutes under the same standards. See, e.g., Lam v. Gen. Mills, Inc., 859 F. Supp. 2d 1097, 1103 (N.D. Cal. 2012); Guttmann v. La Tapatia

Tortilleria, Inc., No. 15-2042, 2015 WL 7283024, at *5-6 (N.D. Cal. Nov. 18, 2015); Robinson v. Unilever U.S., Inc., No. 17-3010, 2019 WL 2067941, at *4-5 (C.D. Cal. Mar. 25, 2019).

MSPRC asserts that their UCL claims arise under the unfair and unlawful conduct prongs, which are subject to the more lenient pleading standards of Rule 8, and thus do not require actual knowledge. Pl. Opp. at 71, ECF No. 134. However, courts have routinely rejected this argument where, as here, the underlying claims sound in fraud. See Kearns v. Ford Motor Co., 567 F.3d 1120, 1125 (9th Cir. 2009) (rejecting a plaintiff's arguments that its claims were not grounded in fraud and finding that the plaintiff's UCL and CLRA claims required application of Rule 9(b)); Kowalsky v. Hewlett-Packard Co., No. 19-2176, 2011 WL 3501715, at *9 (N.D. Cal. Aug. 10, 2011) (applying the Rule 9(b) pleading standard to claims under all three prongs of the UCL where "Plaintiff's remaining UCL and CLRA claims are premised on allegations that HP knew, or should have known, of an inherent design defect in the 8500 Printer and falsely advertised the product, thereby inducing Plaintiff and thousands of putative class members to purchase a defective product.").

MSPRC's claims center on allegations that the Manufacturing Defendants were actually or constructively knowledgeable about the NDMA contamination in its MCDs, and misrepresented the bioequivalence of their products. FAC ¶¶ 548-49. This clearly constitutes "a unified course of fraudulent conduct," and therefore MSPRC must plead actual knowledge of falsity. Kearns, 567 F.3d at 1125 (citing Vess v. Ciba-Geigy Corp. USA, 317 F.3d 1097, 1103-04 (9th Cir. 2002)); Rice v. Sunbeam Prods., Inc., No. 12-7923, 2013 WL 146270, at *10 (C.D. Cal. Jan. 7, 2013) (dismissing FAL claim as legally insufficient because "plaintiff fail[ed] to adequately allege defendant's knowledge of the purported defect."); Punian v. Gillette Co., No. 14-5028, 2015 WL 4967535, at *31- 37 (N.D. Cal. Aug. 20, 2015) (dismissing UCL, CLRA, and FAL claims that

sounded in fraud because the plaintiff did not allege that the defendants had knowledge of the alleged defect). As this Court already found insufficient allegations of knowledge, MSPRC's California consumer protection statute claims are dismissed.

(2) Indiana

The Manufacturing Defendants next claim that MSPRC's claims under Indiana's Deceptive Consumer Sales Act ("IDCSA"), Ind. Code Ann. § 24-5-0.5.1, et seq., fail because MSPRC did not give Defendants notice or an opportunity to cure, nor did it allege any Defendant intended to defraud or mislead them. Mfr. Def. Mem. at 56. The Court agrees.

The IDCSA is intended to be liberally construed and applied to promote its purposes of (1) simplifying and modernizing the law governing deceptive and unconscionable sales practices; (2) protect consumers from suppliers who commit deceptive and unconscionable sales acts; and (3) encourage the development of fair consumer sales practices. Willis v. Dilden Bros., Inc., No. 21A-378, 2022 WL 571062, at *12 (Ind. App. Feb. 25, 2022). Claims under this law can arise under (1) uncured deceptive acts, which do not require a showing of an intent to defraud or mislead; and (2) incurable deceptive acts, which require such a showing. Zylstra v. DRV, LLC, 8 F.4th 597, 620 (7th Cir. 2021) (quoting Ind. Code § 24-5-0.5-2(7) & (8)). To succeed on a claim for an "uncured deceptive act," the consumer must allege that they gave notice to the supplier and either no offer to cure was made within thirty days after notice or the act was not cured within a reasonable time after the consumer's acceptance of an offer to cure. Ind. Cod. § 24-5-0.5-2(a)(7)(A)-(B).

MSPRC contends that they provided notice and an opportunity to cure to the Manufacturing Defendants because one of the Consumer Plaintiffs, Kristen Wineinger, sent a demand letter to Defendants Granules USA, Inc. and Granules Pharmaceuticals, Inc., in

compliance with the IDSCA. Pl. Opp. at 72, ECF No. 134; ECF No. 95-1; Declaration of Andrew J. Obergfell, at Ex. A. As this Court has already determined that the Consumer Plaintiffs lack standing under the FAC, and there are no allegations that the TPPs sent any IDSCA demand letters to Defendants, the Court finds that MSPRC cannot sustain an "uncured deceptive acts" claim under the IDSCA.

As for MSPRC's claim for an "incurable deceptive act" under the IDSCA, the Court finds that MSPRC has not alleged any "scheme, artifice, or device with intent to defraud or mislead." Ind. Code § 24-5-0.5-2(a). While MSPRC professes that they have alleged an intent to defraud by showing that Defendants were "actively violating cGMPs, despite representing the opposite," Pl. Opp. at 74, ECF No. 134, the Court has already determined that such allegations are insufficient to constitute knowledge of the NDMA contamination, let alone an intent to defraud. The Court therefore dismisses MSPRC's IDSCA claim. See McQueen v. Yamaha Motor Corp., USA, 488 F. Supp. 3d 848, 859 (D. Minn. 2020) (dismissing an IDSCA claim where "Plaintiffs have failed to plead facts sufficiently to plausibly claim that Defendant knowingly or intentionally omitted material facts relating to [a particular] Defect.").

(3) New Jersey

The Manufacturing Defendants next assert that MSPRC fails to state a claim for a violation of the New Jersey Consumer Fraud Act ("CFA"), N.J.S.A. § 56:8-1, et seq., because it cannot show a quantifiable loss, as required by the statute. Mfr. Def. Mem. at 56. This argument is unavailing.

To state a claim under the CFA, a plaintiff must prove three elements: (1) unlawful conduct by a defendant; (2) an ascertainable loss by the plaintiff; and (3) a causal relationship between the unlawful conduct and the ascertainable loss. D'Agostino v. Maldonado, 216 N.J. 168, 184

(quoting Bosland v. Warnock Dodge, Inc., 197 N.J. 543, 557 (2007)). "An ascertainable loss under the CFA is one that is 'quantifiable or measurable,' not 'hypothetical or illusory.'" Id. at 185 (quoting Thiedmann v. Mercedes-Benz USA, LLC, 183 N.J. 234, 248 (2005)).

MSPRC has adequately alleged an ascertainable loss. Specifically, it alleges that the TPPs made payments for MCDs that are now worthless due to their contamination, which is a quantifiable loss. See Bang v. BMW of N. Am., No. 15-6945, 2016 WL 7042071, at *17 (D.N.J. Dec. 1, 2016) (finding a quantifiable loss where plaintiffs alleged their vehicles were worth less as a result of a defect); Marcus v. MBW of N. Am., No. 08-5859, 2010 WL 4853308, at *11 (D.N.J. Nov. 19, 2010) (plaintiffs alleged loss where "the class members got less than what they expected"), rev'd on other grounds, Marcus v.BMW of N. Am., 687 F.3d 583 (3d Cir. 2012). Accordingly, MSPRC's CFA claims will not be dismissed for failure to allege loss at this time.

(4) New York

Lastly, the Manufacturer Defendants argue that MSPRC's claims under New York General Business Law §§ 349-50 ("Section 349" and "Section 350") should be dismissed because MSPRC did not allege causation or injury. Mfr. Def. Mem. at 57-58. The Court disagrees.

Section 349 prohibits deceptive acts and practices, while Section 350 prohibits false advertising. Fishon v. Peloton Interactive, Inc., No. 19-11711, 2020 WL 6564755, at *4 (S.D.N.Y. Nov. 9, 2020). "The only difference between the two is that Section 350 more narrowly targets deceptive or misleading advertisements, while Section 349 polices a wider range of business practices." Id. (quoting Cline v. TouchTunes Music Corp., 211 F. Supp. 3d 628, 636 (S.D.N.Y. 2016)). To assert a claim under either section, "a plaintiff must allege that a defendant has engaged in (1) consumer-oriented conduct that is (2) materially misleading and that (3) [the] plaintiff suffered an injury as a result of the allegedly deceptive act or practice." Orlander v. Staples, Inc.,

802 F.3d 289, 300 (2d Cir. 2015) (alteration in original) (citing Koch v. Acker, Merrall & Condit Co., 18 N.Y.3d 940, 967 (N.Y. Ct. App. 2012)). "An actual injury claim under [s]ection[s] 349 [and 350] typically requires a plaintiff to 'allege that, on account of a materially misleading practice, she purchased a product and did not receive the full value of her purchase.'" Daniel v. Mondelez Int'l, Inc., 287 F. Supp. 3d 177, 195 (E.D.N.Y. 2018) (alterations in original) (quoting Izquierdo v. Mondelez Int'l Inc., No. 16-4697, 2016 WL 6459832, at *7 (S.D.N.Y. Oct. 26, 2016)).

MSPRC has made sufficient allegations to satisfy the elements of Sections 349 and 350. It has pled that the Manufacturing Defendants materially misled the TPPs into making payments for what they thought were MCDs bioequivalent to their RLD, and as a result, they made payments for valueless, contaminated drugs. Moreover, MSPRC has alleged that the TPPs made payments for those MCDs expressly because they thought that they were pure, unadulterated drugs, which suffices to show that they were aware of the deceptive statements at issue. MSPRC need not allege that the MCDs had no therapeutic benefits to show that the TPPs "did not receive the full value of [their] purchase[s]." Daniel, 287 F. Supp. 3d at 195. Accordingly, MSPRC's allegations that the TPPs purchased MCDs from Defendants in reliance on their generic labels are sufficient to state a claim under Sections 349 and 350.

7. Unjust Enrichment (Count Fourteen)

Defendants next challenge whether MSPRC has stated a claim for unjust enrichment, maintaining that MSPRC's allegations are group pleadings and do not satisfy Rule 8(a) and the claims are duplicative of their other legal claims. Mfr. Def. Mem. at 61-64; Pharmacy Def. Mem. at 39-40. The Court agrees in part.

Although the precise elements of an unjust enrichment claim vary among states, the general principles of unjust enrichment set forth in the Restatement (Third) of Restitution and Unjust

Enrichment (2011), October 2020 Update (the "Restatement"), are informative. The Restatement provides three traditional elements to state a claim for unjust enrichment: "(1) the plaintiff conferred a benefit upon the defendant; (2) the defendant had an appreciation or knowledge of the benefit; and (3) the defendant accepted or retained the benefit under circumstances making it inequitable for the defendant to retain the benefit without payment of its value." Restatement § 1, cmt. d. "A limiting factor to the remedy of restitution is that in essence it is supplementary and generally not available if the law provides a remedy in contract." In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig. (In re Valsartan VI), MDL No. 2875, 2021 WL 942117, at *58 (D.N.J. Mar. 12, 2021).

First, the Court finds that MSPRC's unjust enrichment claims are properly pled under Rule 8(a). In the FAC, MSPRC alleges that specific TPPs made payments for contaminated MCDs manufactured by specific Defendants. FAC ¶ 27. Accordingly, the Court disagrees with the Manufacturer Defendants' argument that MSPRC does not "direct allegations to any individual Defendant." Mfr. Def. Mem. at 61; cf. Pereira v. Azevedo, No. 12-907, 2013 WL 1655988, at *12 (D.N.J. Apr. 17, 2013) (dismissing an unjust enrichment claim where a complaint "fails to contain any specific facts suggesting that Plaintiff has paid [the defendant], in particular, any money or otherwise conferred a benefit on [the defendant] for which she expected remuneration").

Second, Defendants argue that MSPRC's unjust enrichment claims must be dismissed in the states that prohibit unjust enrichment claims when there is an adequate remedy at state law for the pleaded conduct, but cite only to the laws of California, Indiana, New Jersey, and New York. Mfr. Def. Mem. at 62-63.[27] Defendants are correct that in two of those four states, a plaintiff

[27] As stated previously, it is incumbent on the Defendants to specifically brief the law of each state when seeking to dismiss Plaintiffs' claims.

cannot proceed on an unjust enrichment claim when other possible legal claims and remedies lie against the defendants. Collins v. eMachines, Inc., 202 Cal. App. 4th 249, 250 (Cal. App. 2011) ("[E]quitable relief (such as restitution) will not be given when the plaintiff's remedies at law are adequate."); Fed. Treasury Enter. Sojuzplodoimport v. Spirits Int'l N.V., 400 F. App'x 611, 613 (2d Cir. 2010) ("Unjust enrichment is an equitable claim that is unavailable where an adequate remedy at law exists.").

However, Indiana and New Jersey law is much less clear. For Indiana, the Manufacturing Defendants cite only to Zoeller v. E. Chi Second Century, Inc., 904 N.E.2d 213, 220-21 (Ind. 2009), which stands for the proposition that parties to a contract cannot also recover for unjust enrichment. See also Steak n Shake Enters. v. Varsnon Grp., No. 09-404, 2011 WL 5075135, at *7 (S.D. Ind. Oct. 24, 2011) ("Under Indiana law, it is well-settled that a claim for unjust enrichment is foreclosed where a contract governs the relationship between the parties, because their contract would provide the complainant with an adequate remedy at law." (emphasis added)). Moreover, there is no clear authority to show that Indiana bars unjust enrichment claims for plaintiffs who do not have a contractual remedy against the defendants. Walsh Constr. Co. v. Advanced Explosives Demolition, No. 17-160, 2018 WL 10667912, at *4 (S.D. Ind. July 13, 2018) ("[Defendant] has provided no authority that a quantum meruit/unjust enrichment claim fails as a matter of law when there exists no express contract between the parties to that claim. And Indiana law is to the contrary.").

In New Jersey, while some courts have dismissed unjust enrichment claims where there is an adequate remedy at law, others have been reluctant to do so at the motion to dismiss stage. Compare Santiago v. Total Life Changes LLC, No. 20-18581, 2021 WL 5083835, at *12-13 (D.N.J. Nov. 2, 2021) (dismissing unjust enrichment claims where they "are identical to their

claims for breach of warranty," thereby showing an "adequate remedy at law") with Coyle v. Hornell, No. 08-2797, 2010 WL 2539386, at *5 (D.N.J. June 15, 2010) ("It is true that restitution for unjust enrichment is an equitable remedy that is unavailable when a plaintiff has an adequate remedy at law. However, it is equally true that plaintiffs are permitted to plead alternative theories of recovery." (citation omitted)) and In re K-Dur Antitrust Litig., 338 F. Supp. 2d 517, 544 (D.N.J. 2004) (finding dismissal of plaintiff's unjust enrichment claim premature despite the availability of other adequate remedies at law). The Court finds that MSPRC's claim is pled in the alternate to the other claims in the FAC, and pursuant to Rule 8(d)(2) of the Federal Rules of Procedure, MSPRC's claim may go forward under New Jersey law. [28]

The Court dismisses the unjust enrichment claims under the laws of California and New York.[29] MSPRC's unjust enrichment claims under Indiana and New Jersey law may proceed.

8. Negligence & Negligence Per Se (Counts Sixteen & Eighteen)

Defendants lastly argue that MSPRC's negligence and negligence per se claims must be dismissed because MSPRC failed to sufficiently allege proximate cause and injury and because

[28] Defendants may renew their arguments concerning whether MSPRC can proceed on unjust enrichment and its other claims under New Jersey law at summary judgment.

[29] MSPRC asserts that its unjust enrichment claims should not be dismissed because (1) they may plead an unjust enrichment claim in the alternative. Pl. Opp. at 92-93, ECF No. 134. However, courts in California and New York have specifically rejected this argument when an adequate remedy at law exists. See, e.g., Shuman v. SquareTrade Inc., No. 20-2725, 2021 WL 5113182, at *30-31 (N.D. Cal. Nov. 3, 2021) ("Because a plaintiff seeking restitution on a UCL claim must plausibly allege that legal remedies are insufficient, the UCL claim as current pled in the FAC fails to state a claim [for unjust enrichment]."); Bourbia v. S.C. Johnson & Son, Inc., 375 F. Supp. 3d 454, 466 (S.D.N.Y 2019) (observing that while New York law allows plaintiffs to plead unjust enrichment in the alternative, if it "is duplicative of the other causes of action," i.e. "it relies on the same conduct that forms the basis of [] other claims" "it should be dismissed"). Finally, MSPRC's argument that its unjust enrichment claims should proceed because they seek to redress different harms is unsupported by any law, as it seeks to recover money damages on both its legal and equitable claims.

pure economic loss is not recoverable in California, New York, Indiana, and New Jersey. Mfr. Def. Mem. at 58-61; Pharmacy Def. Mem. at 26-33. The Court agrees in part.[30]

To state a claim for negligence, a plaintiff must allege "(1) a duty of care; (2) a breach of that duty; (3) actual and proximate causation; and (4) damages." Jersey Cent. Power & Light Co. v. Melcar Util. Co., 212 N.J. 576, 594 (2013) (citing Stanley Co. of Am. v. Hercules Powder Co., 16 N.J. 295, 315 (1954)). "The concept of negligence per se allows a litigant, and ultimately a court, to invoke a statute to supply elements of a negligence (e.g. duty and breach), when a defendant violates a statute that is designed to prevent the particular harm at issue and meets other applicable criteria." Kindercare Educ. LLC v. N.J. Fire Equip., No. 16-4211, 2019 WL 1326890, at *7 (D.N.J. Mar. 25, 2019) (citation omitted).

First, Defendants' assertions that MSPRC has failed to allege proximate cause and injury are essentially the same arguments raised in the context of standing. Specifically, they contend that MSPRC "ha[s] not identified a single batch or lot from which they allegedly purchased or consumed MCDs, and thus cannot allege that such MCDs allegedly contained nitrosamines above regulatory limits" and cannot show injury because they did not allege that MSPRC "must have either not used the MCD and suffered an economic loss of its value, or taken it and suffered an ill effect." Mfr. Def. Mem. at 59-60. For the reasons already articulated, namely that the TPPs have specifically identified the Defendants and alleged that the contaminated MCDs they paid for were worthless, the Court has found sufficient allegations of causation and injury to allow MSPRC's negligence and negligence per se claims to proceed.

[30] The Manufacturer Defendants again argue that these claims are subsumed by the PLA, which the Court has already rejected, see supra Section IV.D.

With respect to the economic loss doctrine, the common law of some states provides that "a defendant is not liable in tort 'for any purely economic loss caused by its negligence.'" Residences at Ivy Quad Unit Owners Ass'n v. Ivy Quad Dev., 179 N.E.3d 977, 983 (Ind. 2022). California, New York, Indiana, and New Jersey have all adopted some version of this rule. See Kalitta Air, LLC v. Cent. Texas Airborne Sys., Inc., 315 F. App'x 603, 605 (9th Cir. 2008) (recounting that to recover for a purely economic loss, a plaintiff must allege "(1) personal injury, (2) physical damage to property, (3) a special relationship existing between the parties, or (4) some other common law exception to the rule"); Praxair, Inc. v. General Insulation Co., 611 F. Supp. 2d 318, 326 (W.D.N.Y. 2009) ("The New York Court of Appeals has limited tort recovery based on product failure by holding that when a plaintiff suffers damages resulting from a nonaccidental cause, such as deterioration or breakdown of the product itself, the injury is properly characterized as 'economic loss' and the plaintiff is relegated to contractual damages."); Residences at Ivy Quad, 179 N.E.3d at 981 ("[T]he longstanding rule under Indiana law is that a defendant is not liable in tort when a plaintiff alleges only purely economic loss, which is a financial harm arising from the failure of the product or service to perform as expected." (internal quotation marks omitted)); Minn. Life Ins. Co. v. Cooke, No. 20-14326, 2021 WL 5122070, at *22-23 (D.N.J. Nov. 4, 2021) (observing that "[t]he economic loss doctrine bars negligence claims when the party asserting the action has a contractual remedy," unless "the injured party would not otherwise have a remedy" or if the breaching party owes an independent duty imposed by law (citation omitted)).

MSPRC emphasizes that its claims could fall within one of the exceptions recognized by these states, and any determination of whether the economic loss doctrine applies should occur after full discovery, as the exceptions to the doctrine can involve fact-intensive determinations. Pl. Opp. at 87, ECF No. 134. However, MSPRC has not made any allegations to support the

application of any exception for which discovery would support—for example, MSPRC has made no allegations of a special relationship between the TPPs and the Manufacturing Defendants, nor identified any independent legal duties to support the application of an exception to the doctrine. Therefore, because MSPRC's alleged damages stem only from financial harm arising from the contamination of the MCDs, and it is not clear how discovery would warrant the application of any exception, the Court finds that MSPRC's negligence and negligence per se claims under the laws of California, New York, New Jersey, and Indiana are dismissed.

V. CONCLUSION

For the reasons stated above, Defendants' Motions to Dismiss, ECF Nos. 132, 133, are each **GRANTED IN PART** and **DENIED IN PART**. All claims asserted by the Consumer Plaintiffs—Counts One, Three, Five, Seven, Nine, Eleven, Thirteen, Fifteen, Seventeen, Nineteen, and Twenty-One—are **DISMISSED WITHOUT PREJUDICE** for lack of standing. Of the remaining claims asserted by MSPRC, Counts Four under New York law, Six, Eight, Ten, Twelve under California and Indiana law, Fourteen under New York and California law, Sixteen under New York, Indiana, California, and New Jersey law, Eighteen under New York, Indiana, California, and New Jersey law, and Twenty are **DISMISSED WITHOUT PREJUDICE** for failure to state a claim. The FAC is **DISMISSED WITHOUT PREJUDICE** for lack of personal jurisdiction over the Foreign Defendants. To the extent Plaintiffs can cure the deficiencies identified in this Opinion, they may file an amended pleading within thirty (30) days. An appropriate order follows.

Date: March 30, 2022

/s/ *Madeline Cox Arleo*
Hon. Madeline Cox Arleo
UNITED STATES DISTRICT JUDGE